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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,938	03/19/2004	John Link	10031165-1	8132

7590 06/06/2006

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EXAMINER	
CROW, ROBERT THOMAS	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,938	LINK ET AL.	
	Examiner	Art Unit	
	Robert T. Crow	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Petition

The Petition for color drawings, filed 19 March 2004, if objected to because the paragraph in the Specification regarding color drawings must be the first paragraph of the brief description of the drawings. Appropriate correction is required.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 16 May 2006 is acknowledged. The traversal is on the ground(s) that claims 1-15 are directed to a method for preparing an RNA sample, not a particular RNA, while claims 16-19 are directed to a kit used for employing the method of claims 1-15. These arguments are not found persuasive because, as noted on page 2 of the Requirement for Restriction/Election dated 13 March 2006, Group II is the product (i.e., a kit comprising components), whereas Group I is the methods. As Applicant discloses in paragraph 2 on page 7 of the Remarks, Group II has components for use in the method as defined in claims 1-15. However, as stated in the restriction, the components can be used in materially different methods not limited to the method of Group I (e.g., the kit can be used to purify water). Group II and Group I are related as a product (i.e., a kit comprising components) and a process of using the product.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-19 are therefore withdrawn. Claims 1-15 are currently under prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-6 and are indefinite in claims 2-5, which recite the limitations "BTS," "PVDF," "MMM," and "PVP" in lines 2-3 of claims 2, 4, and 5 and in line 1 of claim 3, because they are acronyms, the meanings of which may change over time. It is suggested that each of the claims be amended to recite each of the polymers in each instance by their respective full names.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the

various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) in view of Sutcliffe et al (U.S. Patent No. 5,459,037, issued 17 October 1995).

Regarding claim 1, Colpan et al teach a method of preparing an RNA sample substantially free of contaminants (e.g., a method for purification and separation of nucleic acid mixtures [Abstract, lines 1-2], wherein the nucleic acid is RNA; column 5, line 64-column 6, line 8), comprising the following steps: preparing an RNA sample (column 6, lines 4-8); adding an organic solvent to the RNA sample (e.g., a buffer containing isopropanol is used to wash a column having a sample loaded thereon; Example 1, column 8, lines 4-41); contacting an isolation column with the organic solvent containing RNA sample (e.g., a column comprising a filter material is contacted with a lysate [column 7, lines 30-36] followed by a washing with buffer containing isopropanol [Example 1, column 8, lines 4-41], thereby contacting the column with the RNA sample contained within an organic solvent), wherein said isolation column

comprises a membrane (a mineral substrate that is a membrane; column 6, lines 52-55); and eluting said RNA in a purified form from said column (e.g., RNA is separated and purified; column 6, lines 7-8). While Colpan et al teach the use of nucleic acids formed by chemical reactions (column 6, lines 4-8), Colpan et al are silent with respect to cRNA.

However, Sutcliffe et al teach a method comprising the preparation of a cRNA sample (Abstract) with the added benefit that cRNA allows for the identification of changes in expression of mRNA associated with pathological conditions (Abstract, last 4 lines).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method of Colpan et al with cRNA as taught by Sutcliffe et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in allowing for the identification of changes in expression of mRNA associated with pathological conditions as explicitly taught by Sutcliffe et al (Abstract, last 4 lines).

Regarding claim 14, the method of claim 1 is discussed above. Colpan et al also teach the organic solvent is ethanol (e.g., chaotropic solutions are used to wash the mineral substrate [column 2, lines 11-15], wherein the chaotropic solution contains ethanol; column 5, lines 20-26).

Regarding claim 15, the method of claim 1 is discussed above. Colpan et al also teach said isolation column is an RNA isolation column (e.g., a column comprising a

filter material is contacted with a lysate [column 7, lines 30-36], and RNA is separated and purified; column 6, lines 7-8).

3. Claims 1 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) in view of Sutcliffe et al (U.S. Patent No. 5,459,037, issued 17 October 1995).

Regarding claims 10-13, the method of claim 1 is discussed above. Claims 10-13 are drawn to cRNA that is from about 55-65, 65-75, 75-85, and 85 to ≥95% pure. The claims do not define what the cRNA is purified from so as to define the purity. Because Colpan et al teach the RNA is separated and purified (column 6, lines 7-8), the RNA of Colpan et al is encompassed by the broadly claimed purity of instant claims 10-13.

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) and Sutcliffe et al (U.S. Patent No. 5,459,037, issued 17 October 1995) as defined by Pall Life Sciences (http://www.pall.com/924_25006.asp?sectionid= description ["description page"] and http://www.pall.com/924_25006.asp?sectionid=specifications ["specifications page"]) and further in view of Wang et al (U.S. Patent No. 5,906,742, issued 25 May 1999).

Regarding claims 2 and 3, the method of claim 1 is discussed above. The Specification teaches that MMM membranes are available from Pall Life Sciences (page 15, paragraph 0061). Pall Life Sciences defines MMM membranes as asymmetric

membranes (description page) composed of polysulfone and PVP (specifications page). While Colpan et al teach the column comprises a membrane (column 6, lines 52-55), Colpan et al and Sutcliffe et al are silent with respect to MMM membranes.

However, Wang et al teach the use of solid phases (e.g., microfiltration membrane materials, Abstract, lines 1-2) comprising PVP (i.e., polyvinylpyrrolidone) co-cast with polysulfone (Abstract, lines 7-11) for filtering biological liquids (e.g., whole blood (Abstract, lines 11-12) with the added advantage that the membranes are highly useful in the quick detection of components contained in liquid samples (Abstract, lines 14-16).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method as taught by Colpan et al and Sutcliffe et al with the membrane as taught by Wang et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in the quick detection of components contained in liquid samples as explicitly taught by Wang et al (Abstract, lines 14-16).

Regarding claim 4, the method of claim 3 is discussed above. Wang et al also teach the MMM membrane is an asymmetric membrane comprised of polysulfone and PVP polyvinylpyrrolidone (Abstract).

Regarding claims 5 and 6, the method of claim 3 is discussed above. Wang et al also teach the MMM membrane has a pore size ranging from about 30 μm to about 40

μm on an upper side, and wherein said MMM membrane has a pore size of about 0.8 μm on a lowers side (e.g., the membrane has a pore size around 1.0 μm and opens to about 50 μm; column 10, line 59- column 11, line 1). In addition, the courts have stated where the claimed ranges "overlap or lie inside the ranged disclosed by the prior art" and even when the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have similar properties, a *prima facie* case of obviousness exists (see *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *Titamium Metals Corp. of America v. Banner*, 778 F2d 775. 227 USPQ 773 (Fed. Cir. 1985) (see MPEP 2144.05.01). Therefore, the claimed range of a pore size ranging from about 30 μm to about 40 μm on an upper side, and wherein said MMM membrane has a pore size of about 0.8 μm on a lower side would have been obvious under the pore size around 1.0 μm that opens to about 50 μm as taught by Wang et al.

5. Claims 1 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) and Sutcliffe et al (U.S. Patent No. 5,459,037, issued 17 October 1995) and further in view of Waggoner (U.S. Patent No. 5,627,027, issued 6 May 1997).

Regarding claim 7, the method of claim is discussed above. While Colpan et al teach the purification of labeled of DNA (column 9, example 6), Colpan et al and Sutcliffe et al are silent with respect to labeling RNA.

However, Waggoner teaches the labeling of RNA using cyanine dyes (Abstract) with the added advantage that cyanine-labeled nucleic acids help reduce non-specific binding to irrelevant components in a mixture (Abstract, last five lines).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the method as taught by Colpan et al and Sutcliffe et al with the label as taught by Waggoner with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because such a modification would have resulted in reduction of non-specific binding to irrelevant components in a mixture as explicitly taught by Waggoner (Abstract, last five lines).

Regarding claim 8, the method of claim 7 is discussed above. Waggoner also teach the label is fluorescent (Abstract).

Regarding claim 9 the method of claim 8 is discussed above. Waggoner also the fluorescent label is a cyanine dye (Abstract).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert T. Crow
Examiner
Art Unit 1634

6/1/06

BJ FORMAN, PH.D.
PRIMARY EXAMINER